

REMARKS

Interview Summary

Applicants thank the Examiner for the courtesy of conducting a telephone interview on January 11, and a follow up communication on January 13, 2010 providing U.S. PTO materials relevant to Declarations pursuant to 37 C.F.R. §1.131. The subject of these communications was the Declaration pursuant to 37 C.F.R. §1.131, which was filed with the response filed July 22, 2009.

The Examiner maintains the position that the July 22, 2009 Declaration pursuant to 37 C.F.R. §1.131 is ineffective to establish prior invention of the claimed subject matter and overcome the outstanding rejection under 35 U.S.C. §102(a) over Welch et al. This reference is Welch reference “CZ” as cited on form PTO-1449 filed on May 29, 2007, which is Welch *et al.* (2003), “Neuropeptide Treatment of Genetic and Acquired IBD and Concomitant Brain Activation in Areas Abnormal in Autism,” Society for Neuroscience Abstract, Program No. 318.5, (hereinafter “Welch et al. 2003”). During the interview, the Examiner also indicated that a “Katz” Declaration pursuant to 37 C.F.R. §1.132 is necessary regarding the Welch et al. 2003 reference which is allegedly prior art under 35 U.S.C. §102(a).

The Examiner also maintains the position that the July 22, 2009 Declaration pursuant to 37 C.F.R. §1.131 is ineffective to establish prior invention of the claimed subject matter and overcome the outstanding rejection under 35 U.S.C. §103 over Hollander (US Pub 20060105939, effective date October 3, 2002) in view of NIH News Alert, Swain and Pierce.

Claims status

Claims 1, 8, 17, 21 are pending and stand rejected. Claims 1, 8, 17, 21 were previously presented with the response filed July 22, 2009.

Office Action of October 16, 2009

The Office Action dated October 16, 2009 maintains the rejection of claims 1 and 17 under 35 U.S.C. §102(a) over Welch et al. 2003 reference. The Office Action of October 16, 2009 maintains the rejection of claims 1, 8, 17, 21 under 35 U.S.C. §103 over Hollander in view of NIH News Alert, Swain and Pierce.

The Office Action states that the Declaration pursuant to 37 C.F.R. §1.131 filed with the July 22, 2009 response is ineffective to overcome Hollander or Welch et al. 2003. The Office Action stated that: (1) “[the July 22, 2009] affidavit now indicates that reduction to practice occurred ‘at least prior to October 3, 2002’, however this has already been established by Applicant in the previous two declarations, which clearly stated reduction to practice occurred ‘at least prior to August 17, 2001’”; (2) “[a]gain, as before, there is no evidence of diligence between the earliest date of asserted conception (prior to 8/17/01) and the date of filing (3/11/04)[.]; and (3) that “Applicant’s ‘conception’ in the previous declarations is equivalent to ‘reduction to practice’ in that Applicant made the compositions now claimed.”

Applicants incorporate by reference all arguments and materials presented with the response filed July 22, 2009.

Applicants respectfully traverse that the Declaration pursuant to 37 C.F.R. §1.131 filed with the July 22, 2009 response is ineffective to remove Hollander as prior art.

Regarding (1) and (3), contrary to statement (1) in the Office Action, the previous Declarations asserted conception “at least prior to August 17, 2001” and diligent reduction of the claimed invention to practice. See items 4 and 5 in the Declaration pursuant to 37 C.F.R. §1.131 filed October 13, 2008, and items 4 and 5 in the Declaration pursuant to 37 C.F.R. §1.131 filed October 26, 2007. The July 22, 2009 Declaration is the first Declaration which asserts actual reduction to practice “at least prior to October 3, 2002.” See item 4 in the Declaration pursuant to 37 C.F.R. §1.131 filed July 22, 2009. The July 22, 2009 Declaration is different from the previous Declarations, because the July 22, 2009 Declaration includes new data. These data show that there is reduced c-Fos immunostaining, where c-Fos is a marker of colitis-induced stress reaction, after

administration of secretin and oxytocin. See Exhibit A, at page 2, and Exhibit B, at page 2 of Declaration pursuant to 37 C.F.R. §1.131 filed July 22, 2009. Therefore, these data show the therapeutic effect of the claimed composition. Thus the July 22, 2009 Declaration shows that the therapeutic composition of oxytocin and secretin was actually reduced to practice at least prior to October 3, 2002. In view of this, applicants traverse statement (3) in the Office Action that “conception” in the previous Declarations is equivalent to “reduction to practice.” Therefore, Applicants traverse that the July 22, 2009 Declaration and the previous Declarations show the same information. Accordingly, the July 22, 2009 Declaration under 37 C.F.R. § 1.131 establishes that Hollander does not qualify as prior art to claims 1, 8, 17, or 21 under 35 U.S.C. § 102(e), and therefore can not be used to reject the present claims under 35 U.S.C. § 103(a). Without the Hollander reference, the remaining three references cannot support the rejection. Applicants respectfully request reconsideration of the July 22, 2009 Declaration and withdrawal of the rejections.

Regarding (2) Applicants respectfully traverse that the July 22, 2009 Declaration is ineffective because “there is no evidence of diligence.” Applicants respectfully traverse that diligence must be shown when actual reduction to practice is asserted. The relevant portion of Rule 1.131 (b) states:

“(b) The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained.” 37 C.F.R. §1.131 (emphasis added).

Explaining the language of Rule 131, MPEP §715.07 clarifies, that there are three ways to establish prior invention of the claimed subject matter:

“(A) >(actual)< reduction to practice of the invention prior to the effective date of the reference; or

(B) conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice; or

(C) conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to the filing date of the application (constructive reduction to practice).” See MPEP §715.07.

Thus, it is clear from the plain language of Rule 1.131 and the relevant section 715.07 of the MPEP, that showing of diligence is required when conception prior to the effective date is asserted. Because the language of Rule 1.131 is in the alternative, the diligence requirement does not pertain to factual showing which asserts actual reduction to practice. Thus, when actual reduction is asserted, Rule 1.131 does not require showing of diligence. As discussed supra, the July 22, 2009 Declaration is the first Declaration to assert actual reduction to practice, which is supported by newly presented data.

Accordingly, the July 22, 2009 Declaration under 37 C.F.R. § 1.131 establishes that Hollander does not qualify as prior art to claims 1, 8, 17, or 21 under 35 U.S.C. § 102(e), and therefore can not be used to reject the present claims under 35 U.S.C. § 103(a). Without the Hollander reference, the remaining three references cannot support the rejection. In view of that, Applicants respectfully request reconsideration of the July 22, 2009 Declaration and withdrawal of the rejections.

During the interview, the Examiner indicated that a Katz Declaration is necessary to overcome the Welch et al. 2003 reference. Applicants respectfully traverse. MPEP §715.01(c) states that “Where the applicant is one of the co-authors of a publication cited against his or her application, he or she may overcome the rejection by filing an affidavit or declaration under 37 CFR 1.131. Alternatively, the applicant may overcome the rejection by filing a specific affidavit or

declaration under 37 CFR 1.132 establishing that the article is describing applicant's own work.” See MPEP §715.01(c) (emphasis added). Applicants note that the filing of a “Katz” Declaration under 37 C.F.R. §1.132 is an alternative option to filing a Declaration under 37 C.F.R. §1.131.

As discussed supra, the July 22, 2009 Declaration pursuant to 37 C.F.R. §1.131 shows actual reduction to practice at least prior to October 3, 2002, which is before the date of the Welch et al. 2003 reference. Accordingly, the July 22, 2009 Declaration under 37 C.F.R. § 1.131 and arguments presented in the response filed July 22, 2009 establish that Welch et al. 2003 does not qualify as prior art to claims 1, or 17 under 35 U.S.C. § 102(a), and therefore does not anticipate the claims. In view of that, Applicants respectfully request consideration of the July 22, 2009 Declaration to overcome the Welch et al. 2003 reference and withdrawal of the rejection.

Please charge our Deposit Account No. 08-0219, under Order No. 0019240.00477US2 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: February 16, 2010

/Jane M. Love, Ph.D./ _____
Jane M. Love, Ph.D.
Registration No.: 42,812
Attorney for Applicant(s)

Wilmer Cutler Pickering Hale and Dorr LLP
399 Park Avenue
New York, New York 10022
(212) 230-8800 (telephone)
(212) 230-8888 (facsimile)